UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

ASSOCIATION FOR ACCESSIBLE MEDICINES,

Plaintiff,

vs.

Court File No. 23-CV-02024 (PJS/JFD)

KEITH ELLISON,
in his official capacity as Attorney General of the State of Minnesota

DEFENDANT'S MOTION TO DISMISS

Defendant.

TO: COURT ADMINISTRATOR and ALL COUNSEL OF RECORD:

Defendant Keith Ellison, in his official capacity as Attorney General of the State of Minnesota, moves the Court to dismiss Plaintiff's Complaint for failure to state a claim upon which relief can be granted.

This motion is made pursuant to Federal Rules of Civil Procedure 12(b)(6) and is based upon the files, records, and proceedings herein, including the memorandum of law filed and served herewith.

Signature on Following Page

Dated: July 31, 2023

Respectfully submitted,

KEITH ELLISON
Attorney General
State of Minnesota

/s/ Nick Pladson

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ATTORNEYS FOR DEFENDANT

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Plaintiff,

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KEITH ELLISON,
in his official capacity as Attorney General of the State of Minnesota,

Defendant.

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MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS AND OPPOSITON TO PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

INTRODUCTION

From its earliest days of statehood, Minnesota's efforts to regulate the sale of drugs have been repeatedly upheld as constitutional exercises of the state's police power. *See State v. Red Owl Stores, Inc.*, 92 N.W.2d 103, 108-09 (1958) (collecting cases). Minnesota's most recent endeavor seeks to ensure the affordability of generic prescription drugs by prohibiting manufacturers of generic or off-patent drugs from excessively increasing the price of their drugs delivered, dispensed, or sold to a consumer in Minnesota. 2023 Minnesota Laws chapter 57, article 2 sections 22 to 27 ("the Act").

The Act is one product of a year-long study of the causes and contributors to high drug prices by the Minnesota Attorney General's bipartisan Taskforce on Lowering Pharmaceutical Drug Prices. The Task Force's 93-page report, issued in February 2020, made policy recommendations to lower the cost of prescription drugs for Minnesotans. The recommendations included prohibiting drug manufacturers from charging, or causing to be

charged, unconscionable prices for their prescription drugs sold in Minnesota. Minnesota's Legislature responded by passing the Act, regulating the speed with which generic drugmakers may increase prices for drugs sent and sold to consumers in Minnesota.

Plaintiff Association for Accessible Medicines ("Generic Drugmakers"), a coalition of generic drug manufacturers, insist the Constitution grants them an unfettered right to gouge captive Minnesota consumers for essential medicines, particularly if it does so indirectly, through intermediaries like wholesalers and distributors. The Generic Drugmakers are wrong. Their novel dormant Commerce Clause theories have been rejected by the Supreme Court. *Nat'l Pork Producers Council v. Ross*, 143 S. Ct. 1142 (2023). States can, and do, place valid restrictions on how products are sold within their borders, and how products destined for points within their borders can be manufactured, dispensed, and sold. Minnesota's compelling interest in ensuring Minnesotans' access to affordable generic prescription medications justifies its law barring Generic Drugmakers from engaging in price-gouging with respect to Minnesota-destined drugs.

Accordingly, this Court should deny Plaintiff's motion for preliminary injunction and dismiss Plaintiff's complaint with prejudice.

FACTS EMBRACED BY PLAINTIFF'S COMPLAINT[1]

I. DRUG MANUFACTURERS SET PRICES FOR DRUGS THAT CONSUMERS PAY IN MINNESOTA.

Generic Drugmakers are "the start of the drug-supply chain." (Complaint, ¶ 23.) Generally, they sell their pharmaceutical products to in- or out-of-state distributors, including wholesalers that, in turn, may sell to pharmacies where the drugs are sold to consumers. (*Id.* at ¶¶ 24, 26.) Many of these wholesalers, but not all, are located outside of Minnesota. (*Id.* at ¶ 26.) Though Generic Drugmakers do not typically sell their product directly to pharmacies, such direct-to-pharmacy sales do occur. (Complaint at ¶ 23; Declaration of Noah Lewellen ("Lewellen Decl."), Ex. A. at 11, fig. 2.3.)[2]

Generic Drugmakers set drug prices by promulgating the list price for their products, known as the "wholesale acquisition cost," or "WAC." (Lewellen Decl., Ex. B at 1-2.)[3] Because they are at the start of the supply chain, manufacturers have the most influence over downstream pharmaceutical prices. (*Id.* at 17.) WAC[4] prices are published and advertised to the general public in various trade catalogs, both nationally and in Minnesota. (Lewellen Decl. Ex. B at 1; Lewellen Decl., Ex. A at 17.) Pharmacies, either directly or

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[1] In addition to the assertions in Plaintiff's Complaint, the State refers to public records and documents necessarily embraced by the Complaint. *See Ashanti v. City of Golden Valley*, 666 F.3d 1148, 1151 (8th Cir. 2012); *see also Palmer v. Cnty. of Anoka*, 200 F. Supp. 3d 842, 845, 846 n.1 (D. Minn. 2016).

[2] *See* Complaint at ¶ 23.

[3] *See* Complaint at ¶ 23.

[4] AWP, or "average wholesale price," may also be advertised. AWP is by convention approximately 1.2 times WAC. *Prescription Drug Supply Chains* at 30.

through contracts negotiated by group purchasers, typically purchase manufacturers' drugs from a wholesaler based on a percentage of the WAC. (Lewellen Decl., Ex. A at 12-13, 18-19.) For generic drugs with few competitors, the final payor, such as a patient, pays a price based off the manufacturer-set WAC. (Lewellen Decl., Ex. B at 19.)

II. OUT-OF-STATE GENERIC DRUGMAKERS HAVE PERVASIVE TIES TO MINNESOTA.

For over 60 years, Minnesota has licensed drug manufacturers. Act of April 14, 1961, Reg. Session, ch. 394 §§ 1, 7, 1961 Minn. Laws 602-3; Minn. Stat. § 151.252, subd. 1. Both in- and out-of-state manufacturers must be licensed if their drugs are sold in Minnesota, even if their products are shipped into Minnesota by a third party. Minn. Stat. § 151.252, subd. 1(g); Minn. R. 6800.1400, subp. 3.[5] In the process of obtaining a license, all manufacturers agree to "operate in a manner prescribed by federal and state law and according to Minnesota Rules." *Id.* at 1(d). Out of Plaintiff's 24 regular members, which are all out-of-state generic drug manufacturers, 20 have applied for and obtained current manufacturing licenses from the Minnesota Board of Pharmacy ("Board") for 38 different out-of-state manufacturing facilities.[6] (Complaint, Ex. A; Declaration of Katrina Howard ("Howard Decl."), ¶ 7.)

[5] "A manufacturer that does not ship drugs into this state from any location that it directly operates must still obtain a license according to Minnesota Statutes, section 151.25, if it does business with accounts in this state. Doing business in this state includes any sale of a manufacturer's drug to any individual or business in Minnesota."

[6] The Board has also issued manufacturing licenses to 86 manufacturing facilities located within Minnesota. (Howard Decl., Ex. A.)

Minnesota also requires wholesale drug distributors to be licensed by the Board. Minn. Stat. § 151.47, subd. 1a(f) (requiring "each drug wholesale distributor facility located outside of the state from which drugs are shipped into the state" to be licensed).[7] Similar to manufacturers, wholesalers applying to distribute drugs into Minnesota must, agree to abide by all federal and state laws. *Id.* at subd. 1a(d). While four of Plaintiff's members do not have current drug manufacturer licenses in Minnesota, three previously held them, and all four currently hold Board-issued wholesale distributor licenses. (Complaint, Ex. A; Howard Decl., ¶¶ 8-12, 18.)[8] Thus, all of Plaintiff's 24 members are currently licensed by the Board as drug manufacturers or wholesale distributors, and 13 members hold both licenses. (*Id.*)[9] Accordingly, per long-established Minnesota law, when an out-of-state manufacturer seeks to ship their generic drugs into Minnesota by way of a third-party wholesale distributor, the transaction must occur between two entities that are licensed by the Board.

Although the Generic Drugmakers are not challenging the geographical reach of these two licensing laws, the Act they are challenging has an identical geographical scope.

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[7] Prescription drug wholesalers doing business in Minnesota, whether in-state or out-of-state, have been required to register with the Minnesota Board of Pharmacy for over 70 years. *See* Act of March 2, 1953, Reg. Sess., ch. 75, § 4, 1953 Minn. Laws 101.

[8] The "three largest wholesale distributors who control over 90% of the market" are all licensed by the Board and operate facilities in Minnesota. (Complaint, ¶ 26; Howard Decl., Ex. C.)

[9] The Board also licenses 82 wholesale distributors located in Minnesota. (Howard Decl., ¶ 17.)

Compare Act § 22, subd. 4 *and* § 23, subd. 1, *with* Minn. Stat. §§ 151.252, subd. 1(g) *and* 151.47, subd. 1a(f).

III. MARKET FORCES ALLOW GENERIC DRUGMAKERS TO ENGAGE IN EXCESSIVE PRICE INCREASES.

While Minnesota currently licenses actors in the pharmaceutical supply chain to ensure clean, safe drugs enter its borders, the sale price of drugs sold in Minnesota has historically been unregulated. This lack of regulation has resulted in abusive practices wherein manufacturers have engaged in unfettered price gouging of captive consumers. (Lewellen Decl., Ex. C at 11.)[10] Tetracycline, for example, a generic antibiotic that is widely-prescribed for a diverse array of bacterial infections, experienced a shortage and subsequent market reentry that resulted in a 17,700% price increase. (*Id.* at 13.) The price for Doxycycline, another generic antibiotic, increased over 1,900%. (*Id.*) These increases were unrelated to any increase in production cost but presented an enticing opportunity to raise prices due to a decrease in supply or competition. (*Id.*) One of Plaintiff's members, Teva Pharmaceuticals USA, Inc., has been specifically singled out by the federal Department of Health and Human Services as playing a part in this trend of consolidation and significant price increases. (*Id.* at 12.)

In short, generic drug manufacturers are often insulated from market pressures that would deter or prevent drastic price increases when they face little, if any, competition.

[10] *See* Complaint at ¶ 20.

This market failure creates perverse incentives for companies to maximize profit at the expense of captive consumers who have no choice when they need life-saving medication.

IV. MINNESOTA ACTED TO PROTECT ITS CONSUMERS FROM EXCESSIVE PRICE INCREASES.

The Act prevents generic drug manufacturers from "impos[ing], or caus[ing] to be imposed, an excessive price increase, whether directly or through a wholesale distributor, pharmacy, or similar intermediary, on the sale of any generic or off-patent drug *sold, dispensed, or delivered to any consumer in the state.*" 2023 Minnesota Laws ch. 57, art. 2, §23 (emphasis added). An "excessive price increase" occurs when:

> (1) the price increase, adjusted for inflation utilizing the Consumer Price Index, exceeds:
> (i) 15 percent of the wholesale acquisition cost over the immediately preceding calendar year; or
> (ii) 40 percent of the wholesale acquisition cost over the immediately preceding three calendar years; and
>
> (2) the price increase, adjusted for inflation utilizing the Consumer Price Index, exceeds $30 for:
> (i) a 30-day supply of the drug; or
> (ii) a course of treatment lasting less than 30 days.

Id. at § 23. For example, if the list price for a generic drug was $100 for a 30-day supply, and its list price increased to $115 in the next year, that would not be a violation because the increase was 15%, but not $30. The Act targets truly excessive increases.

The Act also imposes reporting requirements on generic manufacturers whose pricing practices may implicate violations of the Act, penalizes manufacturers from withdrawing drugs from distribution within the state "for the purpose of avoiding the prohibition on excessive price increases," and authorizes the state attorney general to

enforce the Act. *Id.* at §§ 25-26. Finally, the Act requires every manufacturer that "sells, distributes, delivers, or offers for sale any generic drug or off-patent drug in [Minnesota]" to "maintain a registered agent and office within the state." *Id.* at § 24. The Act does not distinguish between in- or out-of-state manufacturers, nor does it reference any out-of-state price.

Plaintiff was aware of the Minnesota Legislature's efforts to pass the Act and testified against the Act on multiple occasions, communicating their interests repeatedly to the Legislature.[11] Nevertheless, the Legislature passed the Act.

SUPPLEMENTAL FACTS APPLICABLE TO DEFENDANT'S OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION[12]

I. THE GENERIC DRUG MARKET REQUIRES EFFECTIVE REGULATION.

In addition to abusive pricing practices, states (including Minnesota) have alleged more nefarious anticompetitive conduct by generic drug manufacturers. Minnesota and 47 other states and territories filed a Complaint alleging that over 30 generic drug manufacturers (eleven of whom are members of Plaintiff) engaged in an overarching conspiracy to fix prices and thwart competition for over 175 generic drugs. State Attorneys

[11] *See, e.g.*, *Generic or off-patent drugs; Excessive price increases prohibited, attorney general authorized to take action against price increases*: *Hearing on HF 17 Before the House Com. Fin. and Pol'y Comm.*, 2023 Leg., 93rd Sess. (Minn. 2023) (statement of Judy Cook, Senior Partner, Cook Strong Sellwood, on behalf of AAM), *available at* https://www.house.mn.gov/hjvid/93/896146 (at 57:22-1:00:00).

[12] To the extent they are not otherwise referenced in or embraced by the Complaint, facts included in this section are presented solely for consideration in the Defendant's opposition to Plaintiff's Motion for a Preliminary Injunction.

General Complaints, *In Re: Generic Pharmaceuticals Pricing Antitrust Litigation*, 17-3768 (E.D. Pa. Nov. 2017).[13] Indeed, Teva and Sandoz recently paid hundreds of millions of dollars to settle price-fixing claims.[14]

Apart from price-fixing, there are numerous examples of generic manufacturers exploiting market failures to impose excessive price increases on their drugs. Between 2010 and 2015, 48 generic drugs experienced an over-500% price increase in a single year. (Lewellen Decl., Ex. D at 14-15.) Report after report has found that excessive price increases are untethered to market pressures, but rather constitute "price gouging" tied to selective acquisitions to monopolize inelastic consumer markets and other anticompetitive behavior. (Lewellen Decl., Ex. E at 5-7.) Notably, it is the minority of generic drugs that experience extreme price increases. (Lewellen Decl., Ex. D at 12.)

Minnesota's own findings reflect this data. After the Minnesota Attorney General convened a task force on drug pricing, he released a report recommending, among other things, laws requiring transparency to evaluate the scope of the problem in Minnesota. (Lewellen Decl., Ex. F.) The Minnesota Legislature subsequently passed its own drug pricing transparency bill, and the first report from the Minnesota Department of Health ("MDH") was issued in early 2023. (Lewellen Decl., Ex. G ("MDH Report").)

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[13] Two other complaints in the multidistrict litigation may be found at 20-CV-03539 (D. Conn. Sep. 9, 2021) and 19-CV-2407 (D. Conn. Oct. 31, 2019).

[14] *E.g.*, Dan Haar, *The huge pharma settlement in CT that's quietly making history*, CT Insider (Dec. 15, 2022), *available at* https://perma.cc/ZB8Q-URHW; Marcy Gordon, *Drugmaker Sandoz Inc. to pay $195 million fine in antitrust case*, PBS (Mar. 2, 2020), *available at* https://perma.cc/Z27G-ELWE.

The MDH Report was consistent with prior generic drug pricing analyses: Generic drug manufacturers engage in abusive pricing, with at least nine examples of price increase of over 50% in a single year, and 127 examples meeting lower criteria. *Id.* at 23. The MDH Report, as with the GAO's study, (Lewellen Decl., Ex. D), found that a minority of manufacturers engaged in extraordinary price increases. (Lewellen Decl., Ex. G at 22-23.) Months after receiving the MDH Report, the Minnesota Legislature passed the Act.

II. GENERIC MANUFACTURERS' PRICING DECISIONS HURT MINNESOTANS.

Pharmacies in Minnesota use manufacturers' nationally-advertised WAC prices to price generic drugs for sale in Minnesota. (*See, e.g.*, Declaration of Randall Armbruster, ¶¶ 9-11.) Excessive price increases hurt consumers in Minnesota and are especially harmful for Minnesotans who are uninsured or underinsured, on a fixed income, and are forced to pay out-of-pocket the exorbitant list price set by manufacturers. (Lewellen Decl., Ex. F at 31-32.) Some consumers are forced to choose between paying for their basic needs or paying for their medications. *(Id.* at 18. "[A]n estimated 9% of Minnesotans—or more than half a million people—had not filled a prescription due to cost in the preceding 12 months according to a 2017 survey. (*Id*. at 19.)

LEGAL STANDARD

I. MOTION TO DISMISS

In reviewing a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the Court must accept as true all of the factual allegations in the complaint and draw all reasonable inferences in the plaintiffs' favor, *Du Bois v. Bd. of Regents*, 987 F.3d 1199, 1202 (8th Cir. 2021), but the Court "need not consider legal conclusions that are couched as factual

allegations," *Viewpoint Neutrality Now! v. Regents of Univ. of Minn.*, 516 F. Supp. 3d 904, 914 (D. Minn. 2021). A claim only survives a motion to dismiss under Rule 12(b)(6) if the claimant has alleged "sufficient factual matter ... to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

II. PRELIMINARY INJUNCTION.

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc*., 555 U.S. 7, 24 (2008) (citation omitted). When deciding a motion for preliminary injunctive relief, a court considers: (1) the moving party's probability of success on the merits; (2) the threat of irreparable harm to the moving party; (3) the balance between this harm and the injury that granting the injunction will inflict on other interested parties; and (4) the public interest in the issuance of the injunction. *Dataphase Sys., Inc. v. CL Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981) (*en banc*). A plaintiff must demonstrate that all four factors weigh in favor of an injunction to be entitled to relief. *Winter*, 555 U.S. at 20.

The court "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief," with particular regard for the "public consequences in employing the extraordinary remedy of injunction." *Id.* at 24 (quotation omitted). "The burden on the movant is a heavy one where, as here, granting the preliminary injunction will give [the movant] substantially the relief it would obtain after a trial on the merits." *Sanborn Mfg. Co. v. Campbell Hausfeld/Scott Fetzer Co*., 997 F.2d 484, 486 (8th Cir. 1993) (quotation omitted).

ARGUMENT

I. THE GENERIC DRUGMAKERS' COMPLAINT SHOULD BE DISMISSED BECAUSE THEIR CLAIMS FAIL AS A MATTER OF LAW.

The Generic Drugmakers challenge Minnesota's Act preventing all generic drug manufacturers from engaging in price-gouging of generic drugs "delivered, dispensed, or sold to consumers in Minnesota." Act, § 23, subd. 1. The claims are based on alleged violations of the Commerce Clause, the Due Process Clause, and the concept of "horizontal separation of powers".

Each of those claims fail. Minnesota's Act does not violate the Constitution's Commerce Clause because it is non-discriminatory: Any requirements or burdens imposed by the law fall equally on in-state and out-of-state generic drug manufacturers, and any extraterritorial effects are incidental and do not evince a discriminatory purpose. Likewise, the Act does not exceed the appropriate bounds of state power because it only applies when a generic drug is delivered, dispensed, or sold in Minnesota, limiting its reach to market participants whose conduct harms consumers in Minnesota. Because the Act does not violate the Constitution, the Generic Drugmakers' entire complaint should be dismissed with prejudice.

This is not the first time the Generic Drugmakers have made such requests to the federal judiciary; indeed, the Generic Drugmakers recently urged the Supreme Court in an *amicus* brief to "make clear . . . that a state violates the Constitution when it imposes legal consequences on private parties based on transactions beyond the state's borders, even if those out-of-state transactions have effects in the state." Brief for Association for

Accessible Medicines as Amicus Curiae, 2022 WL 2288161 at *3, *Nat'l Pork Producers Council v. Ross*, 143 S. Ct. 1142 (2023). The Supreme Court rejected Plaintiff's breathtaking proposal there, and this Court should reject Plaintiff's claims here.

A. The Dormant Commerce Clause Does Not Bar State Laws with Extraterritorial Effects, So Long as They Do Not Discriminate Against Interstate Commerce.

The Supreme Court has long recognized that the Constitution's Commerce Clause (Art. I, § 8, cl. 3) contains a negative command, known as the dormant Commerce Clause, which prohibits "the enforcement of state laws 'driven by . . . economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors.'" *Ross*, 143 S. Ct. at 1152-53 (citation omitted). "This antidiscrimination principle lies at the very core of the Supreme Court's dormant Commerce Clause jurisprudence." *Id.* at 1153 (quotations omitted.) "'[E]xtreme caution' is warranted before a court deploys this implied authority" under the dormant Commerce Clause *Id*. at 1165. "Preventing state officials from enforcing a democratically adopted state law in the name of the dormant Commerce Clause is a matter of 'extreme delicacy,' something courts should do only 'where the infraction is clear.'" *Id*. (quotation omitted).

Prior to *Ross*, the Eighth Circuit recognized plausible dormant Commerce Clause claims where a state statute: (1) clearly discriminates against interstate commerce in favor of in-state commerce, (2) imposes a burden on interstate commerce that outweighs any benefits received, or (3) has the practical effect of extraterritorial control on interstate commerce. *Styczinski v. Arnold*, 46 F.4th 907, 912 (8th Cir. 2022) (quotation omitted).

In *Ross*, however, the Supreme Court reined in its dormant Commerce Clause jurisprudence, realigning its scope with a core antidiscrimination principle. 143 S. Ct. at 1152-53. As *Ross* makes clear, the gravamen of a viable dormant Commerce Clause claim is proof of discriminatory economic protectionism. *Id*. at 1153. State regulations that explicitly discriminate against out-of-state business, in order to benefit in-state business, violate the dormant Commerce Clause. *Id*. at 1152-1153. Challengers attempting to infer discrimination from facially neutral laws may use the "extraterritorial effect" and *Pike* balancing tests to "smoke out" discriminatory in-state protectionism. *Id*. at 1156-1158. But absent direct or indirect evidence of discrimination, a state statute that simply has a practical "extraterritorial effect" does not violate the dormant Commerce Clause. *Id*. at 1157. Critically, nowhere in the Complaint do the Generic Drugmakers allege that the Act discriminates against out-of-state manufacturers. Nor could they.

Absent discriminatory protectionism, Minnesota may exercise regulatory control over "any articles which, in its judgment, fairly exercised, are prejudicial to" the interests of its citizens. *Id.* at 1153, 1157; *see also W. Lynn Creamery Inc. v. Healy*, 512 U.S. 186, 200 (1994) (recognizing. "nondiscriminatory measures . . . are generally upheld, in spite of any adverse effects on interstate commerce").[15]

[15] *See also Maine v. Taylor*, 477 U.S. 131 (1986); *Gen. Motors Corp. v. Tracy*, 519 U.S. 278 (1997) ("States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected."); *City of Philadelphia v. New Jersey*, 437 U.S. 617, 623 (1978) ("[I]ncidental burdens on interstate commerce may be unavoidable when a State legislates to safeguard the health and safety of its people.").

1. *Ross* Defeats the Generic Drugmakers' Commerce Clause Claim.

Despite the Court's *Ross* opinion, the Generic Drugmakers assert the Act violates the dormant Commerce Clause because the Act has "the practical effect of extraterritorial control on interstate commerce." (Complaint, ¶¶ 61, 65, 70 (Counts I).) For all relevant purposes, the Generic Drugmakers' dormant Commerce Clause challenge is functionally identical to the pork producers' claim rejected in *Ross*.

In *Ross*, pork producers challenged a California statute barring in-state sales of pork from breeding pigs that were "confined in a cruel manner." *Ross*, 143 S. Ct. at 1151. Like the pork trade in *Ross*, the federal Legislature has made no move to nationally regulate drug prices. *Id*. at 1152. Just as the pork producers did in *Ross*, the Generic Drugmakers complain that they have little to no role in directing their product to any particular location; once sold to wholesalers, their products are sent "all over to completely different end users." *Id*. at 1151; (Complaint at ¶ 24). Like the pork producers in *Ross*, the Generic Drugmakers protest that the challenged law would require segregating and tracing state-compliant products in the distribution system, requiring expensive operational redesign. *Id.* at 1151; (Complaint at ¶ 44). Finally, and again like the pork producers in *Ross*, the Generic Drugmakers do not assert that the challenged law is discriminatory (it applies to in-state and out-of-state manufacturers equally) but argue the compliance costs on out-of-state producers at the beginning of the supply chain violates the dormant Commerce Clause's "almost per se" prohibition on state laws with the "practical effect of controlling commerce outside the State." *Ross* at 1154; (Complaint, ¶ 74).

Rejecting each of these concerns, the Supreme Court held that its Commerce Clause jurisprudence never supported broad *per se* rules prohibiting nondiscriminatory laws with a "practical effect" of "controlling" extraterritorial commerce like that which the Generic Drugmakers propose. *Ross* at 1155. Noting that in today's "interconnected national marketplace, many (maybe most) state laws have the 'practical effect of controlling' extraterritorial behavior," the adoption of such a *per se* rule would "cast a shadow" over state laws "long understood to represent valid exercises of the States' constitutionally reserved powers." *Id.* at 1155-56.

The Court declared that its prior decisions simply embraced the dormant Commerce Clause's core purpose—prohibiting discrimination against out-of-state commerce in favor of in-state commerce. *Id.* at 1154-55.[16] The only "*specific* impermissible extraterritorial effect" of a state law prohibited by the dormant Commerce Clause was purposeful discrimination against out-of-state economic interests. *Id.* Because the pork producers did not allege that the California law at issue sought "to advantage in-state firms or disadvantage out-of-state rivals," their dormant Commerce Clause claim failed. *Id.* at 1153, 1157; *New Jersey Staffing All. v. Fais*, No. 1:23-CV-02494, 2023 WL 4760464, at *9 (D.N.J. July 26, 2023) (denying a preliminary injunction, finding that *Ross* "rendered the

[16] The Court recognized its prior extraterritoriality cases shared this common discriminatory feature. In *Baldwin*, New York's law discriminated against out-of-state dairy farmers by erecting barriers protecting in-state milk producers. *Ross*, 143 S. Ct. at 1154 (discussing *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935)). In *Brown-Forman* and *Healy*, the laws at issue required out-of-state companies to match in-state prices, which amounted to discriminatory economic protectionism. *Id.* at 1154-55 (discussing *Healy v. Beer Institute*, 491 U.S. 324 (1989) and *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573 (1986)).

'extraterritoriality doctrine' a dead letter: extraterritorial effects alone are no longer sufficient to show a violation of the Commerce Clause.").

The Generic Drugmakers' dormant Commerce Clause claim is similarly defective. First, the Generic Drugmakers fail to allege the Act has an explicit or implicit discriminatory purpose or that it seeks "to advantage in-state firms or disadvantage out-of-state rivals." *Id.* at 1153. Nor could they; the Act falls on in-state and out-of-state manufacturers alike. Second, the Act's price-gouging prohibition only applies to a generic drug "sold, dispensed, or delivered to any consumer in the state" Act, § 23, subd. 1. The Act's plain language does not erect economic barriers to protect in-state generic drug manufacturers at the expense of out-of-state competitors. *See generally,* Act. And it does not seek to regulate "wholly" out-of-state prices. Indeed, the Act is out-of-state-price agnostic; it simply restricts the speed with which manufacturers can increase the price of generic drugs delivered, dispensed, or sold to a consumer in Minnesota. *Id.*

The sole, non-discriminatory, purpose of the Act is to protect Minnesotans from excessive price increases on life-saving medications that they have no meaningful choice other than to purchase. Because Generic Drugmakers do not (and cannot) allege any purposefully discriminatory extraterritorial effect of the Act, and because the dormant Commerce Clause does not provide a vehicle for Plaintiff to enforce a *per se* rule against a state law's extraterritorial effects, Plaintiff fails to state a plausible Commerce Clause violation, and Count I of its Complaint must be dismissed with prejudice.

2. The Generic Drugmakers Fail to State a Plausible Claim Under the Dormant Commerce Clause's *Pike* Test (Count IV).

Failing in its first theory, the Generic Drugmakers retreat to a second by claiming the Act offends the dormant Commerce Clause because the burdens it imposes on interstate commerce are "clearly excessive" in relation to its "putative local benefits." (Complaint, ¶ 58, citing *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970).) But "no clear line separates the *Pike* line of cases from our core antidiscrimination precedents." *Ross*, 143 S. Ct. at 1157 (citation omitted). Instead, *Pike* and its progeny have "turned in whole or in part on the discriminatory character of the challenged state regulations." *Id.*

a. The Generic Drugmakers fail to allege any impermissible burden under *Pike*.

To fall within the "heartland" of the Court's *Pike* progeny, a plausible challenge to a facially non-discriminatory law must allege that its "practical effects in operation would disclose purposeful discrimination against out-of-state businesses." *See Ross*, 143 S. Ct. at 1158; *Pitman Farms v. Kuehl Poultry LLC*, 2023 WL 3853411 at *7, -- F.Supp.3d – (D. Minn. June 6, 2023) (19-CV-3040) (citing *Ross*). Thus, a plaintiff must allege that the regulation's burdens on out-of-state interests reveal "discrimination against interstate commerce at the retail level."[17] *Exxon Corp. v. Governor of Maryland,* 437 U.S. 117, 125

[17] *Ross* noted that "a small number" of Supreme Court "cases have invalidated state laws that appear to have been genuinely nondiscriminatory," but only when the law "would impede *the flow* of interstate goods" like regulations on interstate trucks or trains. 143 S. Ct. at 1158, n. 2 (quotations omitted) (emphasis in original). And even those laws, *Ross* opined, "were enacted at the instance of, and primarily benefit, in-state interests. *Id.* Here, as in *Ross*, "[w]e do not face a law that impedes the flow of commerce. [Pharmaceuticals] are not trucks or trains." *Id.*

(1978). Because the Generic Drugmakers do not claim the Act has a discriminatory impact on interstate commerce, *Pike*'s balancing test is unavailable, and their claim fails just like those in *Ross* and *Exxon*.

Even if *Pike* applied to nondiscriminatory laws, Plaintiff's claim would fail. The Generic Drugmakers erroneously argue the Act requires that "each manufacturer [] make every sale nationwide comply with Minnesota's rules." (Complaint, ¶ 74.) A nondiscriminatory state law's uniform nationwide effect, in and of itself, does not reveal out-of-state discrimination, and does not state a plausible Commerce Clause claim. Even so, the Act does not require national compliance because generic drug manufacturers are free to engage in out-of-state commerce unencumbered by Minnesota regulations. They simply cannot engage in excessive price increases for their drugs they would allow to be delivered, dispensed, or sold in Minnesota. For example, generic drug manufacturers can comply with Minnesota's Act by restricting the geographical resale of batches of drugs they sell to wholesalers, or they could sell their products directly to pharmacies at a non-gouged price. That they do not do so is a business choice they have made, but it is not the only choice available to them.

Indeed, the Generic Drugmakers admit the Act allows for other distribution avenues apart from the rigid national process they prefer, but claim that "restructur[ing] pricing and supply processes to segregate drug products for sale in Minnesota" would result in "significant compliance costs and disruptions to the drug-supply chain." (*Id.*) The Court rejected the same compliance-by-segregation argument from the pork producers in *Ross*. 143 S. Ct. at 1161-62 ("[T]he dormant Commerce Clause does not protect a particular

structure or metho[d] of operation.") (citation omitted). Indeed, the segregation-of-product issues in this case are far less onerous than those faced by vertically-integrated pork producers in *Ross*, who alleged they would need to modify their out-of-state *production* methods to account for California's required treatment of pigs. *Ross* at 1151. Here, the Generic Drugmakers do not claim compliance would require modifying production methods. While state-specific contracting could be required, it is not inevitable, and even if it were, simply putting pen to paper would enable segregating products bound for Minnesota. Under the Court's *Pike* line of cases, this is not a cognizable "substantial burden."

Moreover, when the only alleged burden imposed on interstate commerce is a law's "possible effects on individual [drug] manufacturers," the burden is insufficient to maintain any Commerce Clause challenge. *Pharm. Res. and Mrs. of Amer. v. Concannon*, 249 F.3d 66, 84 (1st Cir. 2001) (citations omitted). Here, the Generic Drugmakers fail to allege that the Act's impact is so broad as to impact all of interstate commerce, rather than a minority of manufacturers that engage in price gouging.

Finally, although they do not allege that the practical effects of the Act reveal a discriminatory purpose, the Generic Drugmakers claim the Act substantially burdens interstate commerce because "drug manufacturers and the wholesale distributors they sell to are overwhelmingly located outside Minnesota" and there are "less burdensome alternatives." (Complaint, ¶¶ 75, 77.) Under this logic, it is difficult to imagine how any one of the 50 states could regulate the in-state sale of any commercial products unless they had some indefinite but substantial number of industry's participants located in their

borders. But in today's modern "interconnected national marketplace" most industries are "overwhelmingly located outside" a single state. *Ross*, 143 S. Ct. at 1156.

Because the Generic Drugmakers have failed to allege any impermissible, indirect burden under *Pike*, they are due no balancing test, and their claim must be dismissed.

b. The ability for Minnesotans to afford medicine is far more important than Generic Drugmakers' ability to price gouge in consolidated markets.

Even if the Generic Drugmakers could assert a cognizable burden, *Pike* requires upholding a statute unless "the burden imposed on such [interstate] commerce is clearly excessive in relation to the putative local benefits." *Pike,* 397 U.S. at 142. When a law's putative benefits include allowing residents to "provide prescription drugs to [State] citizens who could not otherwise afford them," courts acknowledge that the local benefits are "substantial." *Concannon*, 249 F.3d at 84. Courts similarly find States' interest in consumer protection to be substantial, while the possibility of "uncompelled decisions of private parties to exit a given marketplace" as "not a substantial burden on interstate commerce." *Online Merchants Guild v. Cameron*, 995 F.3d 540, 560, n. 8 (6th Cir. 2021) (citations omitted).

Here, the Generic Drugmakers do not allege that *all* generic drug manufacturers in the marketplace will be impacted, but they allege that "several of AAM's Members" intended to raise the price of their generic drugs "in a manner that qualifies as excessive" under the Act but are refraining to do so. (Complaint, ¶¶ 36, 39.) Opposite this speculative, individual burden is the State's overwhelming interest in exercising its sovereign police powers to protect the health of Minnesotans by ensuring generic drugs are not priced out

of reach for individual consumers in Minnesota. Thus, even if a *Pike* analysis were warranted, it would fail.

c. The Act does not impermissibly "directly regulate" generic manufacturers.

The Generic Drugmakers assert that the dormant Commerce Clause broadly prohibits states from "directly regulating commercial activities entirely outside the boundaries of Minnesota." (Complaint, ¶¶ 5-7, 49.) The Generic Drugmakers make the identical argument in seeking a preliminary injunction, which is legally and factually specious for all the reasons by the State *infra* at 28-31, and the State incorporates those arguments here.

B. The Generic Drugmakers Fail to State Plausible Due Process or "Horizontal" Sovereignty Claims (Counts II & III).

1. The Due Process Claim is Meritless Because Generic Drug Manufacturers Intentionally Sell Products for Distribution in Minnesota.

The Generic Drugmakers argue the Fourteenth Amendment's Due Process Clause limits the Minnesota legislature's power to exercise jurisdiction over a party with little or no contact with the state. (Complaint, ¶¶ 50-51 (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462 (1985)). They argue that the "unilateral act of a third party is not sufficient to create the requisite contacts" for a state to exercise regulatory jurisdiction over a party. (Complaint, ¶ 51.) This claim fails because every drug manufacturer whose goods are sold in Minnesota must first seek out and obtain licenses from Minnesota's Board of Pharmacy. In seeking licensure, they voluntarily agree to comply with Minnesota law, including the Act.

Determining whether a legislature's regulatory authority exceeds Due Process is essentially the same as the test for personal jurisdiction or choice-of-law: "There must be at least some minimal contact between a State and the regulated subject before it can, consistently with the requirements of due process, exercise legislative jurisdiction." *Gerling Global Reinsurance Corp. of Amer. v. Gallagher*, 267 F.3d 1228 (11th Cir. 2001). (citation omitted); *see also*, *Watson v. Emps. Liab. Assur. Corp.*, 348 U.S. 66, 72 (1954). To avoid encroaching on Due Process limitations, "the economic penalties that a State … inflicts on those who transgress its laws, whether the penalties take the form of legislatively authorized fines or judicially imposed punitive damages, must be supported by the State's interest in protecting its own consumers." *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 572 (1996). And, when a State's own citizens are harmed within its borders, the State's police-power interest in regulating and providing redress is at its zenith. *Hill v. Colorado*, 530 U.S. 703, 715 (2000) (health and safety concerns are a "traditional exercise" of State police power).

When a business "deliberately extend[s] into" a state, the Due Process clause allows the state to exercise general jurisdiction over that entity. *Ford Motor Co. v. Montana Eighth Judicial Dist. Ct.*, 141 S. Ct. 1017, 1027 (2017). Even though a state may lack contact with a regulated entity regarding a specific transaction—like an out-of-state drug sale to an out-of-state wholesaler that ends up being delivered, dispensed, or sold to a consumer in Minnesota—it is sufficient for the state to exercise jurisdiction over that company if they otherwise avail themselves of the state's market for the same or similar products in other ways. *Id*. at 476-77.

As an initial matter, the Generic Drugmakers are not small, intra-state operators, but multinational actors that manufacture and distribute generic drugs to a national market that includes Minnesota. They "sell their products to large national wholesaler distributors, who then resell those products to retail pharmacies, hospitals, or other healthcare facilities." (Complaint, ¶ 24.). They implicitly concede that at least some of their drugs are sold directly to entities in the state. (Complaint, ¶ 8 ("AAM's members … sell their drug products to wholesale distributors that are *overwhelmingly* located outside Minnesota."), ¶ 26 ("The vast *majority* of sales … occur outside Minnesota), ¶ 38 ("The AAM members … sell those medicines *overwhelmingly* …outside Minnesota. Some of those medicines are eventually resold to consumers in Minnesota.")(emphasis added).; (De Gavre Decl., ¶¶ 4, 8 (admitting direct sales to Minnesota hospital systems, physicians, or specialty pharmacies with physical presence in Minnesota).)

But we need not parse the Generic Drugmakers' contacts in Minnesota to find jurisdiction; if a generic manufacturer's drugs are sold in Minnesota, that manufacturer must seek and obtain a Minnesota license for that privilege. And indeed, the vast majority of Plaintiff's regular members hold (or held) manufacturing licenses from Minnesota's Board of Pharmacy and voluntarily agreed to comply with Minnesota law.[18] (Howard Decl., ¶¶ 4 & 15, Exs. B & D.) Those Generic Drugmakers that lack a manufacturing

[18] To the extent Plaintiff's members' generic drugs are being produced or sold into Minnesota and they do not have a manufacturing license, they are currently operating in violation of state law. *See* Minn. Stat. § 151.252.

license either previously held a manufacturing license or currently hold a wholesaling license. (*Id.*, ¶¶ 8, 18.)

Not only do the Generic Drugmakers admit they avail themselves of Minnesota's generic drug market by making (some) direct sales into the state, they also sought out manufacturing or wholesale distributing licenses from the Board of Pharmacy and voluntarily agreed to comply with Minnesota law, including the Act. Accordingly, the Act falls well within Minnesota's established legislative jurisdiction to regulate entities that deliver, dispense, or sell prescription drugs to consumers in Minnesota, and easily comports with the Due Process Clause.

2. Plaintiff's Fail to Allege a Plausible "Horizontal" Sovereignty Claim

The Generic Drugmakers wrongly suggest that *Ross* and *Edgar* supply them with an alternative "horizontal separation of powers" claim, which has never been recognized by any precedential opinion. (Complaint, ¶ 70 (Count III).) In *Edgar v. MITE Corp.*, a non-majority of the Supreme Court held that "any attempt 'directly' to assert extraterritorial jurisdiction over persons or property would … exceed the inherent limits of the State's power." 457 U.S. 624, 643 (1982) (plurality opinion). But the Act is distinguishable from the Illinois law in *Edgar* in the same way the Supreme Court distinguished California's humane pork law from *Edgar*. *See Ross*, 143 S. Ct. at 1157, n.1. The Act does not seek to "directly" assert extraterritorial jurisdiction over the Generic Drugmakers, it only subjects them to Minnesota law when their drugs are "delivered, dispensed, or sold to a consumer in Minnesota." Act, § 23, subd. 1.

The Act does not seek to proscribe otherwise lawful conduct occurring in other states, nor does it seek to impose Minnesota law on other sovereigns. It simply sets the terms for any generic drug manufacturers, in- or out-of-state, who participate in Minnesota's market. The Act is a public health and safety law necessary to abate harm caused by excessive price increases imposed by some manufacturers on generic drugs sold in Minnesota; the Generic Manufacturer's compliance with these requirements is an exchange the manufacturers made for the benefit of obtaining a drug-manufacturers license.

The Act is an exercise of state sovereignty that, like any number of nondiscriminatory state consumer protection laws that regulate the price, quality, nature, packaging, or disclosures of products sold to consumers within a state, does not directly regulate out-of-state commerce. Thus, while the Commerce and Due Process Clauses serve as limitations on state power even without congressional implementation, "in the absence of conflicting legislation by Congress, there is a residuum of power in the state to make laws governing matters of local concern which nevertheless in some measure affect interstate commerce or even, to some extent, regulate it." *Hunt v. Washington State Apple Advert. Comm'n*, 432 U.S. 333, 350 (1977) (citation omitted).

Although a state's exercise of that concurrent power necessarily produces out-of-state effects, it would be nonsensical to suggest that the state has thereby invaded another state's sovereignty. Such a rule would severely constrain states' authority to address "local necessities," and resurrect the constitutional theory, long ago rejected by the Supreme Court, that Congress has "exclusive power to regulate commerce" that affects more than

one state. *South Dakota v. Wayfair, Inc.,* 138 S. Ct. 2080, 2090 (2018) (citations omitted). Minnesota simply engaged its police powers to regulate the market for generic drugs within its borders. That compliance with the Act may require Generic Drugmakers to alter their course of business in another state, it does so only to the extent they desire access to consumers in Minnesota, and nothing about the Act renders participation in Minnesota's generic prescription drug market compulsory.

Therefore, the Generic Drugmakers fail to state a plausible claim that Minnesota's Act violates any inherent "horizontal sovereignty" limitation in the Constitution.

C. The Generic Drugmakers Fail to State a Plausible Claim Under Sections 1983 and 1988 (Count V).

Because Plaintiff failed to state any plausible constitutional challenges it necessarily fails to state any plausible entitlement to an injunction, declaratory judgment, or costs or fees under Sections 1983 and 1988.

II. THE GENERIC DRUGMAKERS' MOTION FOR PRELIMINARY INJUNCTION SHOULD BE DENIED BECAUSE THE *DATAPHASE* FACTORS ALL HEAVILY WEIGH IN FAVOR OF DEFENDANT.

The Generic Drugmakers aggressive effort to enjoin Minnesota's democratically adopted price-gouging law under the dormant Commerce Clause runs into an immediate headwind. As the Supreme Court admonished, "extreme caution is warranted before a court deploys this implied authority." *Ross*, 143 S. Ct. at 1165. "Preventing state officials from enforcing a democratically adopted state law in the name of the dormant Commerce Clause is a matter of 'extreme delicacy,' something courts should do only 'where the infraction is clear.'" *Id.* (citations omitted). Against the backdrop of clear Supreme Court precedent, the

Generic Drugmakers cannot demonstrate any likelihood of success on the merits, they cannot meet the other *Dataphase* factors, and their motion for preliminary injunction must be denied.

A. The Generic Drugmakers Have No Likelihood of Success on the Merits.

Because "[s]tate and federal statutes are the output of 'presumptively reasoned democratic processes, where a preliminary injunction is sought to enjoin" a government's legislative act, the movant must satisfy a heightened standard, that they are "likely to prevail on the merits," *Eggers v. Evnen*, 48 F.4th 561, 565 (8th Cir. 2022) (quotations omitted). For the reasons explained *supra* in Section I—which Defendant incorporates by reference here—the Generic Drugmakers cannot show they are likely to prevail. Indeed, they have failed to state a claim upon which relief can be granted at all.[19] (*See supra* at pp. 11 to 27.)

The Generic Drugmakers' entire argument for an injunction is the claim that the Act *directly* (rather than through its practical effects) regulates wholly out-of-state commerce. They claim *Ross* reaffirmed this is a *per se* violation of the dormant Commerce Clause. This argument misconstrues the nature of the Act, the Supreme Court's *Ross* decision, and the dormant Commerce Clause cases preceding *Ross*.

First, the Generic Drugmakers strain to distinguish the nature of the Act from the California statute at issue in *Ross*. (PI Mem. at 13.) Yet, as explained *supra*, both laws operate in the same manner—they prohibit, for police power purposes, the in-state

[19] The Generic Drugmakers do not advance any due process arguments in their motion for preliminary injunctive relief. (*see* Complaint Count II).

distribution of certain consumer products that have offending characteristics (i.e., cruel confinement of pigs and excessively price-gouged generic drugs).

Second, the Generic Drugmakers err like the petitioners in *Ross*, reading "too much into too little" from the Supreme Court's opinions. 143 S. Ct. at 1155. They erroneously claim that footnote 1 in *Ross* approved a *per se* prohibition on state laws that "*directly* regulated out-of-state transactions," purportedly established in *Edgar*. 457 U.S. at 641-43. (PI Mem. at 13.) Generic Drugmakers fail to acknowledge, however, that the "directly regulate" language they fixate on from *Edgar* was only dicta from a plurality decision—a fact recognized in *Ross*. *Edgar*, 457 U.S. at 626 (holding that Part V-A is not the opinion of the Court). Despite the Generic Drugmakers suggestion, the Supreme Court did not adopt a "distinct" dormant Commerce Clause prohibition from *Edgar's* plurality decision.

Moreover, even if the Generic Drugmakers were correct (they are not), they conveniently ignore the second part of this prohibition, which provides that direct regulation of out-of-state transactions is problematic if, and only if, the transacting parties have "*no* connection" to the regulating state. *Ross*, 143 S. Ct. 1157, n. 1 (emphasis in original). This is simply not the case with respect to Minnesota's Act. All manufacturers and wholesale distributors seeking to avail themselves of Minnesota's generic drug market must be licensed by the state. (Howard Decl., ¶¶ 2-3, 13-14.)[20] Indeed, the vast majority of

[20] Additionally, as Plaintiff discusses extensively, the Act also requires manufacturers to maintain an in-state registered office. (PI Mem. at 16-17; Act. § 24). Plaintiff, however, neglects to mention that all of its members sought out and hold licenses from Minnesota's Board of Pharmacy to engage in activities regulated or referenced by the Act.

Generic Drugmakers are licensed manufacturers with the Board of Pharmacy because they desire to direct the generic drugs they manufacture into Minnesota. (Howard Decl., ¶¶ 7-8, Ex. A.) The Act only regulates prescription drugs destined for consumers in Minnesota. Thus, even assuming the *per se* rule exists barring direct regulation of extraterritorial transactions with no connection to the state, it would not apply to this case.

Finally, the Generic Drugmakers reliance on dormant Commerce Clause cases from various circuits that pre-date *Ross* are unavailing. As explained *supra*, the laws at issue in *Baldwin*, *Brown-Forman*, and *Healy* violated the dormant Commerce Clause because their *specific* extraterritorial effect revealed a discriminatory protectionist purpose. Here, the Generic Drugmakers do not argue Minnesota's Act discriminates against interstate commerce. To the extent other courts[21] cited by the Generic Drugmakers erroneously interpreted this trio of cases to strike down non-discriminatory state laws just because of their extraterritorial effects, *Ross* conclusively closed the door on any such *per se* dormant Commerce Clause violation.

The Generic Drugmaker's reliance on *Styczinski* and *Frosh* are equally misplaced. The Eighth Circuit's *Styczinski* decision involved a dissimilar law that discriminated against out-of-state bullion traders, and purported to travel with Minnesotans who engaged in transactions that never touched the inside boundaries of the state. 46 F.4th at 913. It also

[21] Cases cited by the Generic Drugmakers at pages 15-16 and footnote 18 of their memorandum all misinterpret *Brown-Forman* and *Healy* for the overly-broad proposition that state statutes will be struck down if their practical effect is to control conduct outside the state.

applied an overly broad interpretation of the extraterritoriality doctrine since rejected by *Ross*. Here, the Act is limited to drugs actually "sold, dispensed, or delivered to any consumer *in the state*." Act, § 23, subd. 1. This "in the state" limitation is exactly what the Eighth Circuit found missing from the law in *Styczinski*. 46 F.4th at 913.

The same problem afflicted Maryland's price-gouging law in *Frosh*. There, the Fourth Circuit struck down a generic drug price-gouging law, in part, because it applied to drugs "made available for sale" to Maryland residents, regardless of whether or not the transaction "result[ed] in a single pill being shipped to Maryland." *Frosh*, 887 F.3d at 671. Again, Minnesota's Act is materially different from the law in *Frosh* because it *only* prohibits excessive price increases on drugs "delivered, dispensed, or sold to any consumer in the state." Act, § 23, subd. 1. In any event, the dormant Commerce Clause analysis advocated by *Frosh*'s vigorous dissent—rather than its majority—was the framework ultimately adopted by the Supreme Court in *Ross*.[22] *See Frosh*, 887 F.3d at 686-89 (dissent, J. Wynn).

Because the Generic Drugmakers are unlikely to prevail on the merits of their dormant Commerce Clause claim, this factor strongly weighs in favor of denying preliminary injunctive relief.

[22] The Generic Drugmakers note the Supreme Court cited *Frosh*'s decision approvingly in *Ross*. (PI Mem. at 13.) But the Supreme Court only cited *Frosh* (and other circuit decisions) for the unremarkable proposition that lower courts cited the *Baldwin*, *Brown-Forman*, and *Healy* trio of cases to invalidate discriminatory state laws. *See Ross*, 143 S. Ct. at 1155-56. By doing so, the Supreme Court in no way considered or approved of the extraterritoriality analysis or holding in *Frosh*.

B. The Generic Drugmakers Have Not Suffered Irreparable Harm.

The Generic Drugmakers do not face irreparable harm, which occurs "when a party has no adequate remedy at law, typically because its injuries cannot be fully compensated through an award of damages." *Chlorine Inst., Inc. v. Soo Line R.R.*, 792 F.3d 903, 914–15 (8th Cir. 2015) (quotation omitted). To show irreparable harm, "a party must show that harm is certain and great and of such imminence that there is a clear and present need for equitable relief." *Dakotans for Health v. Noem*, 52 F.4th 381, 392 (8th Cir. 2022).

The Generic Drugmakers claim two types of irreparable harm if the Act is not enjoined: (1) a presumed irreparable injury imposed "by any unconstitutional regulation;" and (2) monetary harm from either complying with, or violating, the Act. (PI Mem. at 18-20.) Neither claim has merit.

First, the Generic Drugmakers cite no binding Eighth Circuit precedent for their contention that a presumption of irreparable harm exists when a party demonstrates likelihood of success on the merits of a dormant Commerce Clause claim. The Eighth Circuit's decision in *Ng* involved the individual right to equal protection under the law.[23] *See Ng v. Bd. of Regents of Univ. of Minn.*, 64 F.4th 992, 998 (8th Cir. 2023) (citing *Elrod v. Burns*, 427 U.S. 347, 373-74 (1976) (involving deprivation of First Amendment individual rights)). The Eighth Circuit has not extended a presumption of irreparable harm

[23] The District of Minnesota decisions cited by Generic Drugmakers (PI Mem. at 18) that presumed irreparable harm existed upon a party establishing a likelihood of succeeding on the merits of their Commerce Clause claims are non-binding and rely on opinions outside the Eighth Circuit for this proposition.

to Commerce Clause claims. To hold otherwise would render meaningless the Supreme Court's direction that "any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers from a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (quotation omitted).

Second, the Generic Drugmakers irreparable monetary harm claims are speculative, and unsupported.[24] They allege they must either comply with the Act and "lose revenue" or violate the Act and suffer enforcement actions and "financial penalties." (PI Mem. at 20.) But a record filled with speculation, not evidence, is insufficient to demonstrate irreparable harm. *Gander Mountain Co. v. Cabela's, Inc.*, No. CIV 06-2857 PJS/RLE, 2006 WL 2788184, at *2 (D. Minn. Sept. 26, 2006) (citing *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 602 F.2d 150, 154 (8th Cir. 1979) (finding speculative damages do not justify preliminary injunctive relief)). In support of their compliance loss-of-revenue assertions, Generic Drugmakers have submitted declarations from just two of their twenty-four members, Sandoz, Inc. ("Sandoz") and, curiously, Teva Pharmaceuticals USA, Inc. ("Teva") (PI Mem. at 19.)

Sandoz and Teva will refrain from imposing excessive price increases for just three generic drugs in the second half of 2023.[25] (Redacted Declaration of Timothy De Gavre,

[24] Plaintiff's contention that the Act's "notice-and-reporting regime" will cause unrecoverable costs is completely speculative and unsubstantiated. (*Compare* PI Mem. 19 *with* Galownia Decl., ¶ 21 *and* de Gavre Decl., ¶ 21.)

[25] Given the lack of any other filed declarations, the Act presumably would have no negative impact on the revenues of the Generic Drugmakers' other twenty-two members,

Doc. 20 ("De Gavre Decl."), ¶¶ 14, 16; Redacted Declaration of Kevin Galownia, Doc. 18 ("Galownia Decl."), ¶¶ 10-11, 15-16.) Both companies claim that their intended price increases would violate the Act's limit but provide no evidence substantiating any increased costs that would require a price increase to the level claimed. (*Id.*) Sandoz contends that its drug's current prices "will no longer be profitable given the increased input costs." (de Gavre Dec.. ¶ 15.) But Sandoz never asserts that a price increase that complies with the Act would render the drug unprofitable, and neither does Teva. *See generally*, (de Gavre Decl.) Teva, moreover, points to a variety of pre-existing market and regulatory factors that also "could make it unprofitable for Teva to manufacture its generic prescription drug products." (Galownia Decl., ¶¶ 18-22.) Accordingly, the Generic Drugmakers "lost revenue" claims are speculative, unsubstantiated, and insufficient to establish irreparable harm. *Travel Tags, Inc. v. UV Color, Inc.*, 690 F. Supp. 2d 785, 800 (D. Minn. 2010).

Additionally, Teva is not currently licensed by the Minnesota Board of Pharmacy as a manufacturer. (Howard Decl., Ex. A.) Accordingly, regardless of the Act's application, Teva cannot currently manufacture generic drugs and send them, directly or indirectly, to consumers in Minnesota. Minn. Stat. § 151.252; (Howard Decl., ¶ 6.) Moreover, because Teva is licensed as a wholesale distributor in Minnesota, they are currently exempt from the Act. Therefore, in its capacity as a licensed wholesale distributor, Teva will not be

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the vast majority of whom are licensed manufacturers with the Board of Pharmacy and have agreed to abide by Minnesota law, including the Act. (Howard Decl., ¶¶ 4, 8.)

harmed by the Act.[26]

Finally, the Generic Drugmakers have not alleged any imminent enforcement of the Act, which requires that the Commissioner of Health provide notice to drugmakers in potential violation. Act, § 25, subd. 1. When no such imminent enforcement risk is pending, "irreparable harm" has been inadequately pled. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992).

Because Teva is not a licensed drug manufacturer in Minnesota, the only relevant irreparable harm evidence Plaintiff proffers is from Sandoz: a single generic drug manufacturer claiming speculative harm from its inability to impose excessive price increases on a single generic drug. Plaintiff fails to marshal sufficient evidence of irreparable harm to justify striking down a state's consumer protection law. Because the Generic Drugmakers have not demonstrated irreparable harm, this factor also strongly weighs in favor of denying preliminary injunctive relief.

C. A Preliminary Injunction Is Not in the Public Interest.

The balance of equities and the public interest factors merge when the government is the party opposing the motion for an injunction. *Nken v. Holder*, 556 U.S. 418, 435 (2009). "The public interest is . . . served by maintaining the ability to enforce [a] law adopted by the Minnesota Legislature. . . ." *Carson v. Simon*, 978 F.3d 1051, 1061 (8th Cir. 2020). Here, the public interest is vast and grossly outweighs any countervailing

[26] Teva's Vice President of Pricing Operations admits, however, that Teva manufactures generic prescription drugs that are delivered into Minnesota via wholesale distributors. Teva has not been a licensed drug manufacturer in Minnesota since 2008. Therefore, Teva is admitting violations of Minnesota law. (Galownia Decl. ¶ 5.; Howard Decl., ¶ 6.)

interests of the Generic Drugmakers.

The dysfunctional generic drug market is rife with manufacturer pricing abuses ranging from alleged widespread conspiracies to fix artificially high prices on hundreds of drugs;[27] to unfairly exploiting market failures by imposing shocking price increases;[28] and pursuing detrimental business models that depend on charging exorbitant prices on captive consumers who have no choice but to purchase life-saving medications.[29]

The Minnesota Legislature passed the Act to protect the health and safety of its consumers, like the 9% of Minnesotans – more than half a million people – who did not fill a prescription in past 12 months due to cost. (Lewellen Decl., Ex. F at 19.) Granting a preliminary injunction to the Generic Drugmakers would substantially harm the public interests served by the Act—which includes preventing the above abuses and making life saving generic drugs both accessible *and* affordable to Minnesotans. Ensuring consumers in Minnesota are not forced to choose between food and housing or their health-preserving medicine is a vital public interest. (*Id.* at 18.) Accordingly, the final *Dataphase* factors also strongly weigh in favor of denying the Generic Drugmakers preliminary injunction.

CONCLUSION

The Generic Drugmakers have not shown a fair chance of prevailing on any of its claims and have not made the showing required to obtain a preliminary injunction.

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[27] *Supra* at 8.

[28] *Supra* at 5-6, 9-10.

[29] *Supra* at 5-6, 9-10.

Moreover, the Generic Drugmakers' constitutional claims all fail as a matter of law in accordance with the Supreme Court's recent decision in *National Pork Producers Council v. Ross*, 143 S. Ct. 1142 (2023). Accordingly, Defendant requests this Court deny the Generic Drugmakers motion for a preliminary injunction in its entirety, and dismiss their complaint with prejudice.

Dated: July 31, 2023

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